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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/873,234	06/04/2001	Ernesto Palazzini	9457-023	4468

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PENNIE AND EDMONDS
1155 AVENUE OF THE AMERICAS
NEW YORK, NY 100362711

EXAMINER	
LEWIS, PATRICK T	

ART UNIT	PAPER NUMBER
1623	10

DATE MAILED: 05/07/2002

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 09/873,234	Applicant(s) PALAZZINI ET AL.	
	Examiner Patrick T. Lewis	Art Unit 1623	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on _____ .

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) 1-29 is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) 1-29 is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) 3 .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: .

DETAILED ACTION

Priority

1. Applicant's claim for domestic priority under 35 U.S.C. 119(e) is acknowledged.

Claim Objections

2. Claims 1 and 8-24 are objected to because of the following informalities: A space should be added to "100mg" and "1000mg" after last numeral of the number in the third line of claim 1. The period in the term "mg." should be removed in claims 1 and 8-24. Appropriate correction is required.

3. Claims 28-29 are objected to under 37 CFR 1.75(c) as being in improper form because a multiple dependent claim cannot depend from any other multiple dependent claim. See MPEP § 608.01(n). Accordingly, the claims have not been further treated on the merits.

Claim Rejections - 35 USC § 112

4. The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

5. Claim 27 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Claim 27 recites the limitation "method of claim 15" in the first line of claim 27. There is insufficient antecedent basis for this limitation in the claim.

Claim Rejections - 35 USC § 102

6. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

7. Claims 1-10 are rejected under 35 U.S.C. 102(b) as being anticipated by Cristofori et al. US 5,252,339 (Cristofori).

Cristofori discloses pharmaceutical compositions for oral use comprising sulodexide (column 3, lines 34-43). Therapeutic dosages contain 25 to 250 mg sulodexide (column 3, lines 20-22). The composition may be in the form of tablets or capsules (hard or soft) (column 4, lines 12-34).

8. Claims 26-27 are rejected under 35 U.S.C. 102(b) as being anticipated by Marchi et al. US 5,496,807 (Marchi).

Marchi discloses pharmaceutical compositions of sulodexide for the treatment of diabetic nephropathy. The dosage is comprised of 500-1500 LRU per day (column 3, lines 6-8). The composition may be in the form of tablets, capsules, granulates, or syrups for oral administration (column 3, lines 1-5).

Claim Rejections - 35 USC § 103

9. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and

the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

10. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

11. The factual inquiries set forth in *Graham* **v.** *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

12. Claims 1-27 are rejected under 35 U.S.C. 103(a) as being unpatentable over Cristofori et al. US 5,252,339 (Cristofori), Marchi et al. US 5,496,807 (Marchi), and Baggio et al. US 5,686,432 (Baggio).

Claims 1-25 are drawn to pharmaceutical compositions comprising from about 100 mg to about 1000 mg of sulodexide. Claims 26-27 are drawn to a method of treating diabetic nephropathy comprising administering 100 to 1000 mg/day of sulodexide or a pharmaceutically acceptable salt.

Cristofori discloses pharmaceutical compositions for oral use comprising sulodexide (column 3, lines 34-43). Therapeutic dosages contain 25 to 250 mg sulodexide (column 3, lines 20-22). The composition may be in the form of tablets or capsules (hard or soft) (column 4, lines 12-34).

Cristofori does not teach dosages of sulodexide greater than 250 mg. Cristofori does not teach a controlled-release composition. Cristofori does not disclose the treatment of diabetic nephropathy.

Baggio teaches dosages of up to 500 mg of sulodexide (column 2, lines 36-44). Marchi teaches the treatment of diabetic nephropathy by administering sulodexide (Abstract). Marchi also teaches the use of controlled-released compositions (column 3, lines 1-5).

It would have been obvious to one of ordinary skill in the art at the time of the invention to combine the teachings of Cristofori, Baggio, and Marchi to arrive at the instant invention. One of ordinary skill in the art would aware of methods to increase the concentration of an active agent in order to obtain a desired effect. It would have been obvious to use the invention of Cristofori for the treatment of diabetic nephropathy since Marchi teaches compositions of sulodexide for the same purpose. Marchi also teaches the incorporation of the sulodexide compositions into controlled-release formulations. One would have been motivated to do so in order to provide effective treatment since factors such as the extent of the illness and body weight of the patient could render conventional compositions ineffective. Thus, the instant invention is seen to be within the purview of the skilled artisan.

Conclusions

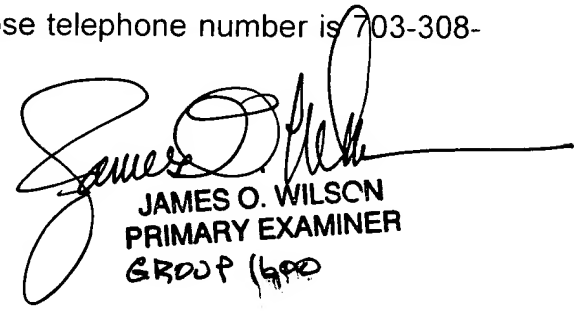
13. Claims 1-29 are pending. Claims 1-29 are rejected. No claims are allowed.

Contacts

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Patrick T. Lewis whose telephone number is 703-305-4043. The examiner can normally be reached on M-F 8:30 am to 4:30 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Johann Richter can be reached on 703-308-4532. The fax phone numbers for the organization where this application or proceeding is assigned are 703-305-3014 for regular communications and 703-305-3014 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0196.



Patrick T. Lewis
Examiner
Art Unit 1623

ptl
April 29, 2002